

Claims 24-54 are pending.<sup>1</sup>

Claims 37-52 have been added. Support for the amendments may be found throughout the specification. No new matter has been added. Specifically, support for the recitation of a "set of oligonucleotides" may be found, for example, at page 11, second full paragraph (set of probes) and page 22, second full paragraph (set of primers). Moreover, probe are defined as consisting of 5-50 nucleotides, with a preferred lower limit of 15, at, for example, page 3, paragraph 6 of the specification. The Examiner is urged to appreciate that neither Lin et al (U.S. Patent No. 5,620,852) nor Martell et al (J. Virol 66 (5): 3225-3229 (May 1992)), for example, disclose or suggest a set of oligonucleotides, as claimed. The length of 21 nucleotides recited in claims 40 and 41, for example, may be found in the disclosure of SEQ ID NO:2, which has a length of 21 nucleotides. Similarly, the length of 27 nucleotides recited in claims 27 and 42, finds support, for example, in SEQ ID NO:1, which is 27 nucleotides in length. The applicants note that SEQ ID NO:43 of the cited Resnick reference has 26 nucleotides. Support for claims 48 and 49 may be found, for example, in the teaching that SEQ ID NOs: 20 and 27 are universal primers which would be useful for amplification of part of the 5'UTR. No new matter has been added.

The Section 112, second paragraph, rejection of claims 25, 30-31 and 36 is obviated by the above amendments. Specifically, the objected-to recitations of

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<sup>1</sup> The undersigned's previous indication in the Amendment of May 28, 2002 that claims 24-45 were pending is unfortunate and any confusion caused by the same is regretted.

"preferably" and "degenerate" and "such as" have been deleted. The misspelled word "n" has been deleted. Withdrawal of the Section 112, second paragraph, rejection is requested.

The Section 102 rejection of claims 25 and 35 over Resnick (U.S. Patent No. 5,527,669) is obviated by the above amendments which no longer recite SEQ ID NO:4 (claim 25) or SEQ ID NOs: 20 and 27 (claim 35). Reconsideration and withdrawal of the Section 102 rejection of claims 25 and 35 over Resnick are requested.

The Section 102 and alternate Section 103 rejections of claim 25 over Lin (U.S. Patent No. 5,620,852) or Martell are obviated by the above amendments. As noted above, the cited art fails to teach or suggest a set of oligonucleotides, as presently claimed. Reconsideration and withdrawal of the Section 102 and alternate Section 103 rejections of claim 25 over Lin or Martell are requested.

The Section 102 and alternate Section 103 rejections of claims 26, 28-29 and 35 over Cha (U.S. Patent No. 6,297,370) are obviated by the above amendments. While SEQ ID NO:80 of Cha may be capable of hybridizing with the complement of SEQ ID NO:20 of the present application, the applicants do not believe Cha teaches a sequence which hybridizes to SEQ ID NO:20 or the invention of claim 26 of the present application. The methods of claims 28 and 35, which depend from the products of claim 26, are submitted to be similarly distinguished over the cited art. Reconsideration and withdrawal of the Section 102 and alternate Section 103 rejections of claims 26, 28-29 and 35 over Cha are requested.

The Section 103 rejection of claims 27-29 over Resnick (U.S. Patent No. 5,527,669) is obviated by the above amendments as SEQ ID NO:43 of Resnick, as noted by the Examiner, is 26 nucleotides in length and the applicants submit that there was no motivation in the cited art to make the invention of claims 27-29 of the present application. Reconsideration and withdrawal of the Section 103 rejection of claims 27-29 over Resnick are requested.

The Section 103 rejection of claims 30-31 over Resnick (U.S. Patent No. 5,527,669) or Cha (U.S. Patent No. 6,297,370) in view of Uhlen (U.S. Patent No. 5,629,158) is obviated by the above amendments as the rejected claims are dependent on claims 28 and 29, respectively, which are submitted to be patentable for the reasons noted above. Reconsideration and withdrawal of the Section 103 rejection of claims 30-31 over Resnick or Cha in view of Uhlen is requested.

Reconsideration and withdrawal of the Section 103 rejection of claim 34 over Lin or Cha or Resnick or Martell in view of Stratagene Catalog is requested as the kit of the rejected claim includes products which are submitted to be patentable over the art of record, for the reasons noted above.

The Examiner is requested to hold the provisional and actual rejections under the judicially created doctrine of obviousness-type double patenting of the claims noted in ¶¶15-18 of Paper No. 11, in abeyance until allowable subject matter is identified, at which time the applicants will consider filing a Terminal Disclaimer(s) to obviate the same.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested.

Return of an initialed copy of the PTO 1449 Form filed July 6, 2001, pursuant to MPEP § 609, is requested.

The Examiner is requested to list the following documents which have been cited by the Examiner, on a PTO 892 Form, for completeness: Hu et al, EP 531974A; and U.S. Patent No. 5,620,852 (Lin et al - 15 Apr-1997) and Stratagene Catalog (1988).

Return of an initialed copy of the PTO 1449 Form filed herewith which lists references of record in the parent application Serial No. 09/378,900 (now U.S. Patent No. 6,495,670 (also listed on the attached)), pursuant to MPEP § 609, with the Examiner's next communication, is requested. Further copies of the cited references are not believed to be required as the same may be found in the parent application file. The Examiner is requested to advise the undersigned however in the event further copies of any of the cited references are required.

The Examiner is requested to acknowledge the applicants claim to domestic priority.

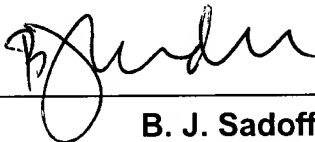
The Examiner is requested to confirm, in his next Action, receipt of the certified copy of the priority documents and acknowledge the claim for foreign priority.

The Examiner is requested to contact the undersigned in the event anything further is required.

**Maertens et al**  
**Serial No. 09/899,082**

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

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**MARKED-UP COPY OF AMENDED AND PENDING CLAIMS  
IN THE CLAIMS:**

Amend the claims as follows:

24. (**Twice** Amended) A polynucleic acid selected from the group consisting of  
CCC TGT GAG GAA CTW CTG TCT TCA CGC (SEQ ID NO 1),  
GGT GCA CGG TCT ACG AGA CCT (SEQ ID NO 2),  
TCT AGC CAT GGC GTT AGT RYG AGT GT (SEQ ID NO 3),  
TTG GGC GYG CCC CCG C (SEQ ID NO 20), and  
TCT GCG GAA CCG GTG A (SEQ ID NO 27),  
or the complement thereof, wherein W represents A or T, R represents G or A,  
and Y represents T or C,  
or a corresponding sequence wherein T has been replaced by U.

25. (**Amended**) A [composition comprising at least one] set of oligonucleotides  
[primer preferably having] comprising at least one oligonucleotide of 15 to 50  
nucleotides, said at least one oligonucleotide comprising at least 15 contiguous  
nucleotides[, with said contiguous nucleotides being] chosen from any of [the following  
sequences:] SEQ ID NOs: 1, 2 or 3 [to 4], or the complement thereof wherein W  
represents A or T, R represents G or A, and Y represents T or C, or a corresponding  
sequence wherein T has been replaced by U.

26. (**Amended**) A polynucleic acid consisting of 10 to 50 nucleotides which  
specifically hybridizes with the sequence of SEQ ID NO:20 [or the complement thereof]

under conditions allowing discrimination of up to 1 nucleotide mismatch] wherein Y represents T or C, or a corresponding sequence wherein T has been replaced by U.

27. **(Amended)** A polynucleic acid consisting of [10] 27 to [25] 50 nucleotides which specifically hybridizes with the sequence of SEQ ID NO 27, or the complement thereof, or a corresponding sequence wherein T has been replaced by U.

28. **(Amended)** A method for detecting the presence of an infection with an HCV virus in a biological sample by means of a hybridization reaction [wherein] with a [polynucleotide] polynucleic acid of any of claims 24, 26 [or], 27, 37 or 39-42 [is used as a probe].

29. **(Amended)** A method for detecting the presence of an infection with an HCV virus in a biological sample by means of a hybridization reaction with a polynucleic acid [according to claim 28 wherein a polynucleotide with the sequence] of SEQ ID NO 20 or 27 or the complement thereof [is used as an HCV specific probe] wherein Y represents T or C, or with a corresponding polynucleic acid wherein T has been replaced by U.

30. **(Amended)** A method according to claim 28 wherein said [hybridization reaction is carried out with said probes which] polynucleic acids are coupled to a solid support[, preferably a membrane, and wherein said probes are optionally capture probes].

31. **(Amended)** A method according to claim 29 wherein said [hybridization reaction is carried out with said probes which] polynucleic acids are coupled to a solid

support[, preferably a membrane, and wherein said probes are optionally capture probes].

32. **(Amended)** A method for detecting the presence of an infection with an HCV virus in a biological sample by means of an amplification reaction using (a set of) primers that specifically hybridize to SEQ ID NO:1 or SEQ ID NO: [2] 3, or the complement thereof wherein W represents A or T, R represents G or A and Y represents T or C; and [to] with SEQ ID NO:2 [3] or SEQ ID NO: 4, or the complement thereof.

33. (Pending) The method according to claim 32 wherein said amplification method is PCR, LCR, NASBA, TAS or amplification by means of Qb replicase.

34. **(Amended)** A diagnostic kit for the detection of HCV in a biological sample comprising at least one of the polynucleic acids of any of claims 24 [to], 26, 27, 37 or 39-42.

35. **(Amended)** A method for the identification of a previously amplified HCV 5' untranslated region fragment comprising hybridizing a polynucleic acid according to any of claims 24, 26, 27, 37 and 39-42 to said [Probe containing up to 50 nucleotides having at least one of the following universal HCV sequences from the] 5'[UR] region [of HCV: SEQ ID NO 20 and 27,

wherein Y represents T or C, or the corresponding sequence wherein T has been replaced by u, or the sequences which are complementary to the above-defined



sequences and with said probe being used for the identification of a previously amplified HCV 5'untranslated region fragment].

36. **(Amended)** Process for general amplification of the 5' UR region of HCV isolates involving at least one of the following [degenerate] primers

a primer of 15 to 50 nucleotides specifically hybridizing with SEQ ID NO: 1 or the complement thereof, wherein W represents A or T, and

a primer of 15 to 50 nucleotides specifically hybridizing with SEQ ID NO:3 or the complement thereof, wherein R represents A or G and Y represents T or C

[a degenerate primer with SEQ ID NO 1, preferably in combination with a primer selected from the region extending from nucleotide -52 to nucleotide -1, such as SEQ ID NO 2, wherein W represents A or T, or the complement of SEQ ID NO 1 or 2,

-a degenerate primer with SEQ ID NO 3, preferably in combination with a primer selected from the region extending from nucleotide -68 to nucleotide -1, such as SEQ ID NO 4, wherein R represents A or G and Y represents T or C, or the complement of SEQ ID NO 3 or 4].

Add the following claims:

--37. (new) A polynucleic acid consisting of 15 to 50 nucleotides which specifically hybridizes with at least one of SEQ ID NO:1, SEQ ID NO:2 or SEQ ID NO:3.

38. (new) A set of oligonucleotides comprising at least a first oligonucleotide of 15 to 50 nucleotides and a second oligonucleotide of 15 to 50 nucleotides, said first